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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,388	12/21/2000	T. William Hutchens	16866002110	3061

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/745,388**

Applicant(s)  
**Hutchens et al**

Examiner  
**Chris Chin**

Art Unit  
**1641**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 29, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 19-61 is/are pending in the application.
- 4a) Of the above, claim(s) 35-38, 40, 41, 48-51, 53, and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-34, 39, 42-47, 52, and 55-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 19-61 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election of cancer (claims 32 and 45) and cationic adsorbent (claims 39 and 52) in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 19-31, 33, 34, 42-44, 46, 47, and 55-61 are generic.

Claims 35-38, 40, 41, 48-51, 53, and 54 are withdrawn from consideration.

### ***Claim Rejections - 35 U.S.C. § 112***

2. Claims 19-34, 39, 42-47, 52, and 55-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is vague. In line 5, the recitation of "resolves" is not clear as to how the adsorbent is supposed to interact with the diagnostic marker. Does the adsorbent bind to the diagnostic marker?

Claim 20 is also vague for the same reasons as claim 19.

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***Claim Rejections - 35 U.S.C. § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 19, 20, 28-30, 33, 34, 42, 43, 46, 47, and 55-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Hutchens et al.

Hutchens et al (U.S. Patent 5,719,060) discloses methods and apparatus for desorption and ionization of analytes for the purpose of subsequent analysis by mass spectrometry, specifically by matrix-assisted laser desorption/ionization to analyze proteins or biomolecules. The analyte can be proteins, peptides, or DNA (col. 12, lines 4-11). The apparatus includes an affinity device comprising a surface (i.e. a substrate) on which the analyte is to be captured. The surface has an affinity reagent that specifically binds to the desired analyte (i.e. an adsorbent) (col. 18, lines 15-27). The affinity reagent can be metal ions, immunoglobulins/antibodies, or nucleic acids (col. 19, lines 1-13). The affinity device can be arranged in a predetermined array and can be made to binds a plurality of different analytes (col. 19, lines 40-45). Example II,

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starting at line 57, discloses an embodiment where antibodies to lactoferrin are used as the affinity reagent to analyze infant urine for the presence of lactoferrin (i.e. a diagnostic marker). Col. 28, lines 50-61, teach analysis of samples derived from blood,, tears, urine, saliva, biopsy tissue, etc. The specific affinity adsorption step cleaned up the analyte from contamination by other components in a complex sample and thus overcomes the signal depression effect when analyte is present in very low concentrations.

***Claim Rejections - 35 U.S.C. § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 31, 32, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens et al.

See above for the teachings of Hutchens et al.

Hutchens et al fails to teach diagnosing a disease, specifically cancer, with the detection of a desired analyte using the disclosed method and apparatus.

However, it would have been obvious to one of ordinary skill in the art to use the method and apparatus of Hutchens et al to diagnose a specific disease, such as cancer, because Hutchens

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et al specifically teaches that the disclosed method and apparatus can be used to analyze biopsy tissue samples for a specific analyte, such as a cancer marker.

7. Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens et al in view of Foster et al.

See above for the teachings of Hutchens et al.

Hutchens et al differs from the instant invention in failing to teach a kit.

Foster et al (U.S. Patent 4,444,879) discloses a kit for performing immunoassays. As shown in Figure 6, the kit contains all of the necessary reagents, apparatus, and instructions for carrying out an immunoassay.

It would have been obvious to one of ordinary skill in the art to place the reagents and apparatus disclosed in Hutchens et al in a kit arrangement, as taught by Foster et al, because kits are well known in the art for their recognized advantages of convenience and economy.

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc  
January 12, 2004

*Christopher L. Chin*  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800 / 641